Chronic Obstructive Pulmonary Disease WINTER 2022-2023 Volume 8 Number 1

DIGEST

Reduced all-cause mortality in the ETHOS Trial of budesonide/glycopyrrolate/formoterol for chronic obstructive pulmonary disease: A randomized, double-blind, multicenter, parallel-group study

American Journal of Respiratory and Critical Care Medicine 2021 Mar 1 ;203(5):553-564

In the phase III, 52-week ETHOS (Efficacy and Safety of Triple Therapy in Obstructive Lung Disease) trial in chronic obstructive pulmonary disease (COPD) (NCT02465567), triple therapy with budesonide/glycopyrrolate/formoterol fumarate (BGF) significantly reduced all-cause mortality compared to glycopyrrolate/formoterol fumarate (GFF). However, 384 of 8,509 patients were missing vital status at Week 52 in the original analyses.

Objectives: To assess the robustness of the ETHOS mortality findings after additional data retrieval for patients missing Week 52 vital status in the original analyses.

Methods: Patients with moderate to very severe COPD and prior history of exacerbation received twice-daily dosing with 320/18/9.6 µg of BGF (BGF 320), 160/18/9.6 µg of BGF (BGF 160), 18/9.6 µg of GFF, or 320/9.6 µg of budesonide/formoterol fumarate (BFF) (all delivered via a single metered-dose Aerosphere inhaler). Time to death (all-cause) was a prespecified secondary endpoint. In the final retrieved dataset, which included Week 52 vital status for 99.6% of the intent-to-treat population, risk of death with BGF 320 was significantly lower than GFF (hazard ratio, 0.51; 95% confidence interval, 0.33–0.80; unadjusted p=0.0035). There were no significant differences in mortality when comparing BGF 320 with BFF (hazard ratio, 0.72; 95% confidence interval, 0.44–1.16; p=0.1721), nor were significant differences observed when comparing BGF 160 against either dual comparator. Results were similar when the first 30, 60, or 90 days of treatment were excluded from the analysis. Deaths from cardiovascular causes occurred in 0.5%, 0.8%, 1.4%, and 0.5% of patients in the BGF 320, BGF 160, GFF, and BFF groups, respectively.

Conclusions: Using final retrieved vital status data, triple therapy with BGF 320 reduced the risk of

The COPD Digest is published by Chronicle Information Resources Ltd. for COPD Canada. Each issue reviews recently published (PubMed) clinical abstracts (Digests) with reviews (Dialogues) written by:
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death compared with GFF but was not shown to significantly reduce the risk of death compared with BFF, in patients with COPD. Triple therapy containing a lower dose of inhaled corticosteroid (BGF 160) was not shown to significantly reduce the risk of death compared with the dual therapy comparators.

Sources: *Fernando J. Martinez, Klaus F. Rabe, Gary T. Ferguson, Jadwiga A. Wedzicha, Dave Singh, Chen Wang, Kimberly Rossman, Earl St. Rose, Roopa Trivedi, Shaila Ballal, Patrick Darken, Magnus Aurivillius, Colin Reisner, Paul Dorinsky*

PubMed PMID: 33252985 PMCID: PMC7924571 DOI: 10.1164/rccm.202006-2618OC Free PMC article

DIALOGUE

Chronic Obstructive Pulmonary Disease (COPD) is the third leading cause of death worldwide and acute exacerbations of COPD (AECOPD) are a leading cause of hospitalizations in Canada. As clinicians, one of our goals of therapy for patients living with COPD is to prevent and/or reduce the frequency of AECOPD. Our belief is that if we prevent these events, patient's will live longer, as there is ample literature suggesting that patients who experience severe exacerbations that require hospitalization or who have recurrent exacerbations are more likely to die in the following one to five years. However, there have been very few high-quality studies assessing this relationship. ETHOS is a large multi-center study assessing the benefit of budesonide/glycopyronium/formoterol (BGF triple therapy) in a single inhaler in preventing AECOPD in patients at a high risk of future AECOPD. All cause mortality (dying from any cause) was also assessed in ETHOS and there was a 46% reduction in patients who were on BGF triple therapy when compared to the dual bronchodilator glycopyronium/formoterol (GFF) but no difference when compared to budesonide/formoterol (BFF), which contains an inhaled corticosteroid and long-acting bronchodilator.

A criticism of the original study was that 384 of the 8,509 patients in the study were missing data about their vital status at the end of the trial, raising concern about whether the findings were valid. For completeness and to assess whether the survival benefit seen in ETHOS held up, the authors of this particular study retrieved the vital status data of these 384 patients to confirm the findings. After repeating the analysis with all additional patients, the authors found similar results which substantiated the survival benefit for patients treated with BGF triple therapy. The survival benefit was sustained throughout the treatment period of the study and not just a result of the study design. This is an important finding. Of interest, in both ETHOS and another important study called IMPACT, there were fewer cardiovascular deaths in patients who were on an inhaled corticosteroid. This finding needs further studies, which are planned, to be fully understood. ETHOS, along with IMPACT, are important because they have both demonstrated that improving the survival of patients living with COPD should be an additional goal for both patients and clinicians, and when the right medicines are used in the right patient, this goal is achievable. **MB**

DIGEST

CONQUEST quality standards: For the COllaboration on QUality improvement initiative for achieving Excellence in STandards of COPD care

International Journal of Chronic Obstructive Pulmonary Disease 2021 Aug 12; 16:2301-2322

Chronic obstructive pulmonary disease (COPD) is managed predominantly in primary care. However, key opportunities to optimize treatment are often not realized due to unrecognized disease and delayed implementation of appropriate interventions for both diagnosed and undiagnosed individuals. The COllaboratioN on QUality improvement initiative for achieving Excellence in STandards of COPD care (CONQUEST) is the first-of-its-kind, collaborative, interventional COPD registry. It comprises an integrated quality improvement program focusing on patients (diagnosed and undiagnosed) at a modifiable and higher risk of COPD exacerbations. The first step in CONQUEST was the development of quality standards (QS). The QS will be imbedded in routine primary and secondary care, and are designed to drive patient-centred, targeted, risk-based assessment and management optimization. Our aim is to provide an overview of the CONQUEST QS, including how they were developed, as well as the rationale for, and evidence to support, their inclusion in healthcare systems.

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Methods: The QS were developed (between Nov. 2019 and Dec. 2020) by the CONQUEST Global Steering Committee, including 11 internationally recognized experts with a specialty and research focus in COPD. The process included an extensive literature review, generation of QS draft wording, three iterative rounds of review, and consensus.

Results: Four QS were developed: 1) identification of COPD target population, 2) assessment of disease and quantification of future risk, 3) non-pharmacological and pharmacological intervention, and 4) appropriate follow-up. Each QS is followed by a rationale statement and a summary of current guidelines and research evidence relating to the standard and its components.

Conclusion: The CONQUEST QS represent an important step in our aim to improve care for patients with COPD in primary and secondary care. They will help to transform the patient journey, by encouraging early intervention to identify, assess, optimally manage and follow up COPD patients with modifiable high risk of future exacerbations.

Source: *Rachel Pullen, Marc Miravitlles, Anita Sharma, Dave Singh, Fernando Martinez, John R. Hurst, Luis Alves, Mark Dransfield, Rongchang Chen, Shigeo Muro, Tonya Winders, Christopher Blango, Hana Muellerova, Frank Trudo, Paul Dorinsky, Marianna Alacqua, Tamsin Morris, Victoria Carter, Amy Couper, Rupert Jones, Konstantinos Kostikas, Ruth Murray, David B. Price*

PMID: 34413639 PMCID: PMC8370848 DOI: 10.2147/COPD.S313498 Free PMC article

DIALOGUE

Underdiagnosis and delayed implementation of appropriate therapies is a common problem for many people with COPD. Quality improvement programs are a set of activities to systematically analyze a set of processes or practices to identify opportunities for improvement, implement change, and evaluate the impact of the change. The CONQUEST program, described by Pullen and colleagues, is a unique international collaboration of COPD experts and quality improvement experts with the aim to improve care of individuals with COPD who are at particularly high risk of exacerbations and poor outcomes associated with them. They propose to do this through a quality improvement program embedded within primary and secondary care practices that will use data captured within electronic medical records, patient-reported information, and outcomes as well as clinical decision support tools (computer algorithms that can help physicians identify patients at high risk of COPD and/or exacerbations, for example) to help facilitate earlier and targeted interventions for high risk COPD patients within their practices. This article describes the four main quality standards and a rationale behind their development and include 1) identification of the target population (QS1), 2) assessment of disease and quantification of future risk (QS2), 3) non-pharmacological and pharmacological intervention (QS3), and appropriate follow-up (QS4). The rationale for the standards described in the article are strong and based on best available evidence for management of COPD across its entire spectrum. A strength of the CONQUEST program is that it will test the success of their quality improvement program based on these quality standards with the hope that the learnings and results can be translated to primary care practices and health systems beyond their program. This is not likely to be the last time we hear about the CONQUEST program. **EP**

Incidence of depression and antidepressant prescription in patients with COPD: A large U.K. population-based cohort study

DIGEST

Respiratory Medicine 2022 May; 196:106804..

Depression is frequently reported in patients with Chronic Obstructive Pulmonary Disease (COPD). However, there is little information available on the incidence of depression following a COPD diagnosis.

Objective: To determine the incidence of a new diagnosis of depression or antidepressant prescription in people with and without a COPD diagnosis.

Methods: A matched cohort study was conducted using The Health Improvement Network database. Patients with confirmed COPD diagnosis were matched to up to four subjects without a COPD diagnosis by age, sex, and GP practice. Cox proportional hazards models were used to assess the incidence rates of depression and antidepressant prescription. .

Results: A total of 44,362 patients with COPD and 124,140 subjects without COPD were included. The incidence rate of depression per 1,000 person-years following COPD diagnosis was greater

(11.4; 95% CI: 10.9-11.8) compared to subjects without COPD (5.7; 95% CI: 5.5-5.8) ($p < 0.001$). Patients with COPD were 42% more likely to have an incident depression (adjusted hazard ratio [aHR]: 1.42; 95% CI: 1.32-1.53; $p<0.001$), and 40% more likely to be prescribed an antidepressant (aHR: 1.40; 95% CI: 1.35-1.45; $p<0.001$). The incidence to either depression or antidepressant prescription was also greater for patients with COPD (aHR: 1.41; 95% CI: 1.36-1.46; $p<0.001$). Patients with COPD and worse breathlessness had a higher risk of incident depression compared to patients with less breathlessness.

Conclusion: Healthcare providers managing patients with COPD should be alert to the existence of depression and aware of its symptoms and consequences.

Source: *R.A. Siraj, T. M. McKeever, J. E. Gibson, C. E. Bolton*

PMID: 35325742 DOI: 10.1016/j.rmed.2022.106804

DIALOGUE

Chronic Obstructive Pulmonary Disease (COPD) is associated with many co-morbidities such as coronary artery disease, congestive heart failure, and osteoporosis. Another important co-morbidity is clinical depression. The current estimated prevalence of depression in individuals living with COPD is between 15-36%. There has been plenty of literature on the co-existence of depression in individuals living with COPD and its impact on their clinical course. Depending on the study and the outcome, people diagnosed with both diseases have a poorer quality of life, reduced exercise capacity, poor adherence to treatment regimens, and may be at higher risk for frequent exacerbations. However, less has been written on the incidence of depression, that is, the new diagnosis of depression, in people already diagnosed and living with COPD. In this study by Siraj, et al, they examined the risk of a new diagnosis of depression or being prescribed a new antidepressant, in individuals newly diagnosed with COPD. Using a large U.K. database, the authors found that people with COPD were 41% more likely to be diagnosed with depression and 40% more likely to be prescribed an antidepressant within six years of a COPD diagnosis versus those without COPD. The risk was greater for women, people with advanced breathlessness (MRC 4-5) and a lower socioeconomic status.

This study is important for a couple of reasons. Given the high rates of new onset depression after a diagnosis of COPD, strategies for the early diagnosis of depression in patients with COPD should be considered given the impact this co-morbidity has on COPD outcomes. Concepts such as routine screening for depression during clinical reviews should be considered. For people with both diseases, there are known interventions, such as pulmonary rehabilitation (PR), that have been clinically proven to improve depression scores, while simultaneously improve the trajectory of a person's COPD. PR is of extreme importance for people with both diseases and both individuals living with COPD and clinicians should advocate for improving access to PR across Canada. **MB**

DIGEST

PRIMUS—PRompt Initiation of Maintenance therapy in the US: A real-world analysis of clinical and economic outcomes among patients initiating triple therapy following a COPD exacerbation

International Journal of Chronic Obstructive Pulmonary Disease 2022 Feb 10; 17:329-342

Patients with chronic obstructive pulmonary disease (COPD) may experience moderate (requiring outpatient care) or severe (requiring hospitalization) disease exacerbations. Guidelines recommend escalation from dual to triple therapy (inhaled corticosteroid + long-acting beta agonist + long-acting muscarinic antagonist) after two moderate or one severe exacerbation in a year. This study examined whether prompt initiation of triple therapy lowers risk of future exacerbations and reduces healthcare costs, compared to delayed/very delayed triple therapy after an exacerbation.

Methods: This retrospective observational study of US healthcare claims included patients ≥40 years old with COPD who initiated triple therapy (1/1/2011 to 3/31/2020) after ≥2 moderate or ≥1 severe exacerbation in the prior year. The earliest of the second moderate or first severe exacerbation was the index date. Patients were stratified by triple therapy timing: prompt (≤30 days post-index), delayed (31-180 days), very delayed (181-365 days). COPD exacerbations, all-cause and COPD-related healthcare utilization and costs were assessed during 12 months post-index (follow-up). Multivariable regression estimated the effect of each 30-day delay in triple therapy on the odds of exacerbations, number of exacerbations, and costs during follow-up, controlling for patient characteristics.

Results: A total of 24,770 patients were included: 7,577 prompt, 9,676 delayed, 7,517 very delayed. Each 30-day delay of triple therapy was associated with 11% and 7% increases in the odds of any exacerbation and a severe exacerbation, respectively (odds ratio [95% CI]: 1.11 [1.10-1.13] and 1.07 [1.05-1.08]), a 4.3% (95% CI: 3.9-4.6%) increase in the number of exacerbations, a 1.8% (95% CI: 1.3-2.3%) increase in all-cause costs, and a 2.1% (95% CI: 1.6-2.6%) increase in COPD-related costs during follow-up.

Conclusion: Promptly initiating triple therapy after two moderate or one severe exacerbation is associated with decreased morbidity and economic burden in COPD. Proactive disease management may be warranted to prevent future exacerbations and lower costs among patients with COPD.

Sources: *Joseph Tkacz, Kristin A. Evans, Daniel R. Touchette, Edward Portillo, Charlie Strange, Anthony Staresinic, Norbert Feigler, Sushma Patel, Michael Pollack*

PMID: 35177901 PMCID: PMC8843423 DOI: 10.2147/COPD.S347735 Free PMC article

DIALOGUE

Severe exacerbations, defined as those requiring admission to hospital, are associated with poor clinical outcomes and make up almost 70% of the costs of COPD. Treatment with triple therapy in randomized clinical trials (inhaled steroids and two long-acting bronchodilators) is associated with reduced frequency and severity of exacerbations and more recently, improved survival among people living with COPD who have frequent and/or severe exacerbations. Studies have shown that prompt initiation of maintenance inhaler therapy after a severe exacerbation is associated with reduced healthcare use and costs, as well as lower risk for future exacerbations; however, many studies have not looked at this association among individuals with COPD with exacerbations not requiring hospitalization.

This study by Tkacz, et al looked at the risk of future exacerbations and added costs associated with delayed initiation of triple therapy after one severe or ≥2 moderate COPD exacerbations. Nearly one-third (30.6%) of patients had prompt (≤30 days), 39.1% delayed (31–180 days), and 30.3% very delayed (181–365 days) initiation of triple therapy. Patients who did not receive triple therapy promptly after their first exacerbation had more comorbidities than patients with prompt initiation of triple therapy and evidence of more severe COPD disease. They were also more likely to be female and covered by Medicaid insurance, indicating lower income levels. Patients with delayed time to triple therapy also had greater odds of experiencing subsequent exacerbations, hospitalization for an exacerbation, and more total events in the subsequent year. Compared to patients with severe exacerbation requiring hospitalization, a higher proportion of patients with ≥2 moderate exacerbations in a year had delayed/very delayed triple therapy (74% vs. 56%) and were more likely to have another exacerbation (80% vs. 67%). This study highlights an important problem, that is, delay in initiating effective therapy is common among COPD patients, particularly those who have more severe disease, comorbidities, and lower income. Furthermore, this delay is associated with worse clinical outcomes. Although this study doesn't tell us why there was delay in initiating therapy for a large proportion of individuals with COPD, it raises concern about equitable access to appropriate care. While this study highlights the experience of a U.S. population, there is no reason to believe that delay in initiating appropriate therapy and factors contributing to it are not relevant to our Canadian population. **EP**

DIGEST

Control of cardiovascular risk factors in patients with chronic obstructive pulmonary disease

Annals of the American Thoracic Society 2022 Jul; 19(7):1102-1111.

Cardiovascular disease accounts for one-third of deaths in patients with chronic obstructive pulmonary disease (COPD). Better control of cardiovascular risk factors in primary care could improve outcomes.

Objectives: To define the prevalence, monitoring, treatment, and control of risk factors in patients with COPD.

Methods: Repeated cross-sectional analysis of primary care electronic medical records for all patients with COPD in the Canadian Primary Care Sentinel Surveillance Network from 2013 to 2018 (n=32,695 in 2018). A control group was matched 1:1 for age, sex, and rural residence

(n=32,638 in 2018). Five risk factors were defined using validated definitions including laboratory results: hypertension, dyslipidemia, diabetes, obesity, and smoking.

Results: All risk factors were more common in patients with COPD compared to matched control subjects, including hypertension (52.3% vs. 44.9%), dyslipidemia (62.0% vs. 57.8%), diabetes (25.0% vs. 20.2%), obesity (40.8% vs. 36.8%), and smoking (40.9% vs. 11.4%), respectively. The mean Framingham risk score was 20.6% vs. 18.6%, with 53.8% of patients with COPD being high risk (≥20%). Monitoring of risk factors within the last year in patients with COPD in 2018 was suboptimal: 71.8% hypertension, 39.4% dyslipidemia, 74.5% diabetes, 52.3% obesity. Smoking status was infrequently recorded in the electronic record. In those monitored, guideline recommended targets were achieved in 60.8%, 46.6%, 57.4%, 10.6%, and 12.0% for each risk factor. Cardiovascular therapies including angiotensin-converting enzyme inhibitors (69%), statins (69%), and smoking cessation therapies (27%) were underused.

Conclusions: In patients with COPD, major cardiovascular risk factors are common, yet inadequately monitored, undertreated, and poorly controlled. Strategies are needed to improve comprehensive risk factor management proven to reduce cardiovascular morbidity and mortality.

Source: *Nathaniel M. Hawkins, Sandra Peterson, Allison M. Ezzat, Rohit Vijh, Sean A. Virani, Andrew Gibb, G.B. John Mancini, Sabrina T. Wong*

PMID: 35007497DOI: 10.1513/AnnalsATS.202104-463OC

DIALOGUE

Cardiovascular disease (CVD) is a common co-morbidity associated with COPD. Although there are many reasons for the development of this relationship, it is the shared risk factor of smoking that is a key driver. CVD is responsible for more deaths in COPD patients than lung cancer. Unfortunately, many therapies used in CVD are underutilized in patients with COPD. An example of this is the underutilization of cardio-selective beta blockers in COPD patients, despite their documented safety and therapeutic benefits when appropriately used. In this study by Hawkins, et al, they examined the prevalence and achievement of guideline recommended targets for the major CVD risk factors including hypertension, diabetes, cholesterol, smoking, and obesity in patients who also have a diagnosis of COPD. Using a Canadian Primary Care database of more than two million patients, they found that individuals with a COPD diagnosis were twice as likely to have co-existing CVD conditions such as a history of prior heart attack, atrial fibrillation, or stroke. They found that CVD risk factors were more common in people living with COPD than those without COPD. Further to this, the majority of COPD patients Framingham risk score was calculated to be in the "high risk" category. The Framingham score is used to predict the likelihood of having a first CVD event of any kind, such as a heart attack or stroke in the next 10 years. Of concern is that routine monitoring of these common CVD risk factors including hypertension, diabetes, and obesity occurred less often in those with COPD than those without COPD. As well, achievement of treatment targets for hypertension, cholesterol, and diabetes were sub-optimal in the COPD group.

This study highlights the urgent need for strategies to improve the assessment and treatment of common CVD risk factors in COPD patients. Treatment of COPD must go beyond the lungs, and include the optimization of important co-morbidities, like CVD, that are known to impact the long-term outcomes of those living with COPD. **MB**

DIGEST

Predictors of premature discontinuation and prevalence of dropouts from a pulmonary rehabilitation program in patients with chronic obstructive pulmonary disease

Respiratory Medicine 2022 Mar; 193:106742.

To date, very little is known about the risk factors that contribute to premature discontinuation (dropout) from pulmonary rehabilitation (PR) in patients with chronic obstructive pulmonary disease (COPD). The researchers examined prevalence and predictors of premature discontinuation in patients who participated in an eight-week PR program.

Methods: They analyzed a prospectively maintained data-base of patients with COPD who attended a PR program from 2013 to 2019. Included were patients 40 years or older with forced expiratory volume in 1 s (FEV1)/forced vital capacity (FVC) ratio less than 0.7. Subjects were assigned com-

pleters or non-completers based on whether they completed the eight-week PR program. Quality of life was measured using the St-George's Respiratory Questionnaire (SGRQ), anxiety using the Anxiety Inventory for Respiratory disease (AIR), dyspnea using the modified Medical Research Council (mMRC) scale, and exercise capacity using the Incremental Shuttle Walk Test (ISWT).

Results: A total of 993 COPD patients (mean age=70.82 years, FEV1=59.21% predicted, 51% male) entered the PR program. Of these, 259 (26%) discontinued PR prematurely and 139 (53%) were male. Compared to completers, non-completers had elevated symptoms of dyspnea and anxiety, had reduced exercise tolerance, were younger, and had poorer quality of life at entry (all $p<0.05$). On multivariate analysis, the following variables were independently associated with discontinuation from PR: younger age ($p<0.001$), elevated symptoms of anxiety ($p<0.001$), elevated symptoms of dyspnea ($p<0.01$), and reduced exercise tolerance ($p<0.002$).

Conclusion: Over one-quarter of COPD patients discontinued the PR program prematurely. Discontinuation of PR was associated with younger age, elevated symptoms of dyspnea and anxiety, and reduced exercise capacity, but not with severity of airflow obstruction.

Source: *Abebaw Mengistu Yohannes, Richard Casaburi, Sheila Dryden, Nicola Alexander Hanania*

PMID: 35091205 DOI: 10.1016/j.rmed.2022.106742

Pulmonary rehabilitation (PR) programs are designed to increase endurance and improve clinical outcomes in COPD patients. PR improves exercise capacity and quality of life and reduces anxiety and depression among people living with COPD. Despite its important benefits, many patients are not referred to PR and not all people with COPD who are enrolled in PR complete the program. This study by Yohannes, et al examined the risk factors for not completing a PR program and how common early discontinuation of the program was seen in a large cohort of COPD patients in the U.K. who were referred to an eight-week PR program. Completion of the program was defined as attending >75% of the aerobic and strengthening sessions as well as completion of the assessment and outcomes visit at week eight. Almost 1,000 patients were referred to the PR program between 2013 and 2019 with 26% not completing the program. Non-completion was associated with younger age, higher symptoms of anxiety and depression, and decreased exercise capacity. Interestingly, the severity of lung function was not associated with non-completion.

This study is important for a couple of reasons: Prior studies have shown that those with reduced exercise capacity and lung function impairment are most likely to gain the largest benefit by attending PR. The study suggests that the people who are most likely to benefit from PR are the most likely to not complete it. The association of higher anxiety and depression among those who do not complete PR suggest that early interventions including cognitive behavioural or relaxation therapies to reduce anxiety may be helpful to include at the beginning of a PR program. **EP**

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The COPD Digest is supported in part by an educational grant from **AstraZeneca Canada**

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Publication Mail Agreement No. 40016917